PREMARKET NOTIFICATION

510(k) SUMMARY

(As Required By 21 CFR 807.92) SEP 3 0 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K112320 Date:2011/8/9

1. Submitter:

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2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL168JD
Common Name: Blood Pressure Monitor
Classification Name: Noninvasive Blood Pressure Measurement System
Classification: Class II, 21CFR 870.1130
Product Code: DXN
Panel: Cardiovascular

3. Information for the 510(k) Cleared Device (Predicate Device):

Full Automatic (NIBP) Blood Pressure Monitor, Model HL168GA, K050714

4. Device Description:

HL168JD automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for over the age of 18 with wrist circumference ranging from approx. 5.3~ 7.7 inch (135 ~ 195 mm) and for home use.

5. Intended Use

HL168JD uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's wrist. All values can be read out in one LCD panel. The device is designed for home use and recommended for use by adults aged 18 years and older with wrist circumference ranging approx. 5.3 ~ 7.7 inch (135 ~ 195 mm).

6. Comparison of device to predicate device:

Product Specification Comparison Table of HL168JD and HL168GA (K050714)

Item	Predicate HL168GA (K050714)	HL168JD
Method of measurement	Oscillometric	Same as left
Measurement range of	Pressure 0- 280mmHg Pulse 40-199 beats/minute	Rated range of cuff pressure: 0- 300mmHg Rated range of determination: 40- 280mmHg Pulse 40-199 beats/minute
Accuracy	Pressure +/− 3mmHg Pulse +/− 5%	Same as left
Inflation	Automatic inflation (Air pump)	Same as left
Deflation of pressure	Automatic air release control valve	Same as left
Display	Liquid Crystal Display	Same as left
Memory	40 memory * 3 users (120 memory total)	30 memory * 3 users (90 memory total)
Cuff size	Wrist circumference approx. 135 ~ 195 mm	Same as left
Operation environment	10℃ ~ 40℃ , 30%~85%R.H.	50°F~104°F (10℃ ~ 40℃), 15%~90% R.H.
Storage/ Transportation environment	- 20℃ ~ + 60℃, 10%~95%R.H.	- 4°F~ +158°F (- 20℃ ~ + 70℃), ≦90%R.H.
Power Supply	2 × "AAA" (1.5V) Alkaline battery	Same as left
Material	ABS housing and rubber keys	Same as left
Number of Push Bottom	5	Same as left
Storage case	Yes	Same as left
Unit Weight	Approx. 133g (Including batteries)	Approx. 166±5g (Excluding batteries)

Changes from the predicate devices HL168GA (K050714):

* 5 push buttons' positions, changing of exterior casing design
* The modification of the dimension of the inflatable bladder and cuff cloth

7. Discussion of Clinical Tests Performed:

HL168JD is compliant to standards of ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/A2:2006/(R) 2008 and AAMI / ANSI / ISO 81060-2:2009. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met. Besides, HL168JD successfully passed the European Society of Hypertension validation according to International Protocol revision 2002 for the validation of blood pressure measuring devices in adults and has been published on dabl website as well.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. **Safety Test:**
   - IEC 60601-1:1988+A1:1991+A2:1995, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
   - IEC 80601-2-30:2009, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

b. **EMC Test:** IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

c. **Biocompatibility Test:**
   - ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
   - ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
   - ISO 10993-10:2002/Amd. 1:2006(E), Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity amendment 1.

d. **Reliability Test:** ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/A2:2006/(R) 2008, Manual, electronic or automated sphygmomanometers.

e. **Risk Assessment:** ISO 14971:2007 Medical devices – Application of usability engineering to medical device.

9. Conclusions:

The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –W066-G609
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Health & Life Co., Ltd.
c/o Mrs. Sarah Su
Manager
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Zhonghe District, New Taipei City
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SEP 30 2011

Re: K112320
Trade/Device Name: Full automatic (NIBP) blood pressure monitor (model HL168JD)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 19, 2011
Received: August 19, 2011

Dear Mrs. Su:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

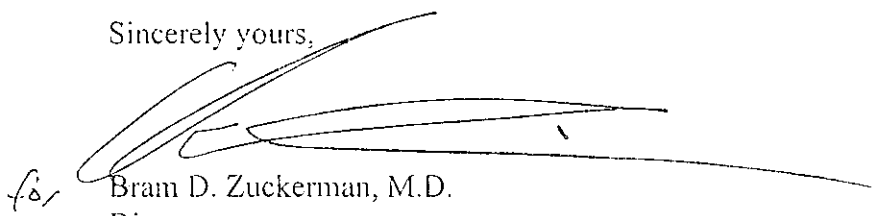
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K112320

Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL168JD

Indications for Use:

HL168JD uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's wrist. All values can be read out in one LCD panel. The device is designed for home use and recommended for use by adults aged 18 years and older with wrist circumference ranging approx. 5.3 ~ 7.7 inch (135 ~ 195 mm).

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __V__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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